HDR GUIDE

INFORMATION REQUIRED FOR LICENSING REMOTE AFTERLOADING DEVICES

NOTE: This document assumes that you have a medical license (limited scope medical license or broad scope license) and you wish to amend your license to permit use of a remote afterloading device. Accordingly, it is not necessary to submit information about calibration of survey instruments, radiation safety committee, personnel monitoring program, leak testing and ALARA program, unless any of these prior commitments change because of this amendment request. Address these changes in your amendment request.

I. Description of the Source(s) and Device(s)

A. Source description*

1. Radionuclide

2. Manufacturer's name and model number**

3. Maximum activity (in curies)

4. Number of sources

B. Device description

1. Manufacturer's name**

2. Model name/number

II. Intended Use

The typical response is "to be used for interstitial and intracavitary treatment of cancer." Any other intended uses, such as " non-human use," should be described.

*If you wish to possess and use more than one radionuclide in the device, provide the information in 1-4 for each radionuclide.

**The supplier can tell you if either the device or the source(s) you propose to use within the device has not had a health and safety review by either the NRC or an Agreement State (i.e., is not listed in the NRCSS "Registry of Radioactive Sealed Sources and Devices"). If the review has not been conducted, please contact the Radiological Health Branch for guidance.

III. Proposed Users

A. If your facility already has physician-users approved for use of the same model HDR on this license, you may simply state that the use of the device will be limited to those individuals.

B. If your facility already has physician-users approved for use of the same model HDR on another NRC or Agreement State license, submit a copy of that license and state that the use of the device will be limited to those individuals

C. If you are a broad scope medical licensee, you should state that your Radiation Safety Committee will approve users for this device who are physicians and meet the criteria in III.D.2.

D. For each proposed (human-use) user who does not satisfy III.A. , III.B. or III.C, you should submit the following:

1. The physician's full name

2. Indicate and submit a copy of certification

a) By the ABR in Radiology or Therapeutic Radiology

b) By the AOBR in Radiation Oncology

c) By the Canadian Royal College of Physicians and Surgeons (RCPS) in Therapeutic Radiology

d) As a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR)

e) If the physician is not board certified in one of the specialties listed in D.2. and has not been previously licensed by NRC or an Agreement State, submit a training and experience form, RH 2010, for each proposed user.

IV. Training for Individuals

A. Provide outline of training given to device operators

B. If you will be performing your own source exchange, describe additional training provided to individuals who will conduct source exchanges, including operating procedures.

C. Provide name, affiliation and qualifications of instructor conducting training in A. and B. above (i.e. manufacturer, or authorized user or medical physicist trained by manufacturer)

D. Confirm that individuals who are trained in the use of the device and have practiced the emergency procedures will be on-site while the device is in use

E. Outline topics covered in retraining and state the frequency of such retraining (minimum annual refresher training required) . Confirm that the retraining will include "dry-runs" of emergency procedures.

F. Commit to documenting all training records for inspection purposes.

V. Facilities

***If the licensee is installing the HDR afterloader unit in an existing linear accelerator (megavoltage) vault shielding evaluations (items 1-6 below) may not be required.**

A. Submit annotated drawing(s) (both plan and elevation) of each treatment room* indicating:

1. Scale
2. Direction of north
3. Identification of room (i.e., room number)
4. Type, density and thickness of all shielding walls, floor, ceiling
5. Location of entrance, windows, conduits, etc.
6. Nature of and distance to adjacent areas
7. Use of adjacent areas (i.e., restricted or unrestricted)

B. Describe Continuous Viewing and Audible Communication System For Each Treatment Room

1. Primary
2. Backup if primary system fails or commit to halting treatments

C. Describe Area Security For Each Treatment Room

1. Describe Electronic Interlocks
2. Restricted area(s) controls (e.g., signs, locks, alarms, lights, etc.)
3. If other radiation-producing devices are in the room, means of assuring and committing to having only one device in operation at a time
4. Means of verifying source "safe" condition (e.g., permanently installed radiation monitor)
5. Confirm that, once tripped, the entry interlock must be reset before activation of device

*Treatment is usually performed in rooms specially constructed or modified for radiation therapy. If use is in an accelerator room, identify operational position of the HDR.

D. Describe Permanently Installed Radiation Monitor

1. Confirm that the monitor is visible upon entry

2. Describe back-up power supply

3. Commit to promptly replacing or repairing the monitor if needed

4. Describe the operability check of the monitor including its frequency

E. Provide Shielding Evaluations, Calculations, Safety Measures For Each Treatment Room

***If the licensee is installing the HDR afterloader unit in an existing linear accelerator (megavoltage) vault theoretical calculations (items 1-3 below) may not be required.**

1. Estimate of maximum "on-time" per hour and per week

2. Calculation of exposure rate in each adjacent area with most adverse source orientation(s) and source combinations

3. For unrestricted areas, the licensee must meet the criteria below:

   a. With "on-time" considered and "occupancy factor"*=1:

      (1) < 2 mR in any 1 hour, AND

      (2) < 100 mR in 1 year

4. For restricted areas, the following should be described:

   a. Physical/administrative control of access

   b. Signs: Location, number, wording

   c. Personnel monitoring

   d. Training

   e. Surveys (instrument type and model number) of patient

VI. Operating Procedures

A. You need not provide a copy of procedures but you need to supply the following minimum commitments:

1. Have implemented written operating procedures

*"Occupancy factor" is used as in NCRP Report No. 49: a factor used to correct for the degree of occupancy of the area in question while the source is in the exposed position.

2. Copies given to appropriate staff and posted at HDR device controls

3. Procedures:

- Require securing unit, console, room when unattended
- Require that only the patient be in room with device activated
- Require that the authorized user be in direct supervision of the HDR operator during treatment
- Require that immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of each survey shall be maintained.

4. Daily (or on each day of use) checks will be performed, documented and will include checks of:

- Reproducibility of source positioning within catheter within $\underline{+1}$ mm
- Verification of source position indicators (e.g., lights, alarms, room monitor)
- Inspection of guide tubes for kinks and other imperfections

5. Monthly checks (or prior to use if used less frequently) of the electronic interlocks will be performed and documented

6. Treatment time calculations and data input will be independently verified and documented before treatment is begun by the authorized user physician (radiation oncologist).

B. Calibration of Source in Device and commitment to documenting them

1. Describe procedures, frequencies and equipment used to determine:
   - Dose accuracy to within +/- 5 percent (monthly or prior to use if used less frequently)
   - Exposure rate (source exchange)
   - Accuracy of timing device (monthly or prior to use if used less frequently)
   - Source travel time error (source exchange)
   - Dosimetry system calibrated by NIST or AAPM approved lab every 2 years

2. Describe qualifications of individual(s) performing calibrations

C. If the device with installed source(s) will be moved from one treatment room to another, describe checks that will be conducted after each move and before use to ensure proper operation of both the device and associated safety systems (e.g., interlocks, lights).

D. Source Exchange

1. Commit to the following:

Subsequent to each source loading, radiation surveys shall be performed prior to human use as follows:

(a) A radiation survey shall be made of the unit source housing, with the source(s) in the shielded position. The maximum radiation levels at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.

(b) Records of survey results shall be maintained for inspection.

E. Preventative Maintenance

1. Commit to following the manufacturer's recommended preventative maintenance schedule.

2. Commit to maintaining records for and only utilizing the manufacturer or those individuals specifically licensed by the NRC, Agreement State or Licensing State to perform HDR preventative maintenance or repairs. Otherwise, submit the qualifications and training of the individual who will perform HDR preventive maintenance or repairs.

VII. Emergency Procedures

Submit a copy of emergency procedures and specify that these procedures will be posted near each place of use. As a minimum, your procedures should include:

- When the procedures are to be followed,
- Step-by-step actions and by whom (including their title) these actions are to be taken,
- Minimizing patient exposure,
- Requirement to secure area; posting warning notice, and
- Providing names and on-duty/off-duty telephone numbers of at least 2 trained individuals to be notified
- A list of on-site emergency equipment that includes at least a lead container, wire cutters and forceps
- (NOTE: Manufacturers are now recommending that wire cutters not be used because of the problem with the source being cut. They now recommend putting the source while attached to the cable into the shielded container until the manufacturer rep arrives to handle the problem.)

VIII. Waste Disposal

Commit to maintaining records and returning radioactive materials to an authorized recipient, such as the source/device manufacturer.

IX. Human Use

Once an amendment has been issued for physical measurements, the licensee may procure the source and perform physical measurements. Prior to human use, the licensee must submit:

- **Physical measurements survey results**
- **Instrument used for performing survey (ion chamber or energy-compensated GM probe)**
- **Date of last instrument calibration**
- **Interlock check result**
- **Alarm monitor check result**
- **How roof access is restricted to members of general public (if applicable)**

REFERENCES

1. Gammamed 12it NRC Sealed Source and Device Registry MA-1056-D-101-S.
2. Nucletron SEL 106 NRC Sealed Source and Device Registry NR-497-D-101-S.
3. Nucletron MicroSelctron HDR-Classic NRC Sealed Source and Device Registry MD-0497-D-104-S.
4. Varian Varisource HDR NRC Sealed Source and Device Registry CA-0661-D-103-S.
5. NRC FC 86-4, Rev. 1 (Draft)